

REMARKS

The Official Action of December 12, 2007, and the prior art relied upon therein have been carefully reviewed. The claims in the application are now claims 1-21, and these claims define patentable subject matter and should be allowed. Favorable reconsideration is therefore respectfully requested.

Acknowledgment by the PTO of the receipt of applicants' papers filed under Section 119 is noted.

Claims 1-3, 8-13 and 18-20 have been provisionally rejected on the basis of obviousness-type double patenting over claims 1, 4 and 6-9 of co-pending application 10/570,499. The provisional rejection is respectfully traversed.

First, the rejection is premature as no claims have been allowed in this application or the co-pending application. Any such rejection should be held in abeyance until claims are found to be free of the prior art and in full conformance with Section 112. Applicants accordingly request that the provisional rejection be withdrawn on this basis alone.

Moreover, the rejection implies, in the discussion of the substitution of Tyr at the 23 position, that the claimed subject matter in at least some of applicants' claims

is identical to what is claimed in the co-pending application, yet this cannot be so because the rejection is only based on obviousness-type double patenting. The rejection is thus unclear.

Next, the rejection states that "in a form for oral administration" in an intended use, but this conclusion is respectfully but forcefully submitted to be incorrect. The claims in question call for a particular form, and that is a structural recitation and not an intended use.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 9-11 and 18-20 have been rejected under the first paragraph of Section 112. The rejection is respectfully traversed.

The present application is directed to those highly skilled in the art. It is based on a foundation of work previously done as pointed out in the background section of the present application, and to some extent in the references cited. The novel and non-obvious advance achieved according to the present invention is broadly outlined in the paragraph at page 7, line 14 through page 9, line 2, and there is nothing there so stated which would be "incredible" to those skilled in the present art. In other words, there is nothing unbelievable in what is stated in applicants' specification,

and those skilled in the art could practice the present invention as broadly as it is claimed.

What is stated in an applicant's specification is to be accepted by the PTO in the absence of evidence or good reasoning to the contrary, neither of which have been presented here.

Applicants' allegations, which are entirely believable, are supported by the experimental results set forth in the examples and shown graphically in the figures. Applicants respectfully note that experiments set forth in an applicant's specification are to be accepted as accurate, and as equivalent to evidence presented in affidavit or declaration form.

Withdrawal of the rejection is in order and is respectfully requested.

New claim 21 has been added which is patentable for the same reasons as the other claims as pointed out above and below, and which finds support in original claims 1 and 4-7, and in the text at page 8, lines 9-12.

Claims 3, 9-11, 13 and 18-20 have been rejected under the second paragraph of Section 112. The rejection is respectfully traversed.

First, some minor cosmetic amendments have been introduced to place certain claims in better form for US practice. No limitations have been added and none are intended.

As to claim 3, the claim ends with the language "in the amino acid sequence of SEB", and applicants believe that the claim is therefore clear.

As to the term "immunopathy", the rejection (also the rejection under the first paragraph of Section 112) states that the term "immunopathy" is not a term of art. Applicants respectfully disagree and note that exactly the same term is used in one of the references applied, namely Sasaki EP 1,055,429. Those skilled in the present art know very well what "immunopathy" means.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1-3, 8-13 and 18-20 have been rejected under Section 102 as anticipated by Sasaki. The rejection is respectfully traversed.

The first, third and fourth aspects of Sasaki appear to be unrelated to the present invention. The second aspect includes possible substitutions at the 23 position including Tyr. However, it is not seen that Sasaki discloses the claimed subject matter, e.g. a modified SEB which inherently

avoids the problem mentioned at the bottom of page 6 of applicants' specification.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1-4 and 9-11 have been rejected under Section 102 as anticipated by Nishi et al, 1997 (Nishi). The rejection is respectfully traversed.

Nishi is acknowledged prior art and is discussed on page 6 of applicants' specification, where it is pointed out that Nishi does not teach how to achieve the success obtained according to the present invention.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1-3, 8-13 and 18-20 have been rejected under Section 102 as anticipated by Kappler et al WO93/14634 (Kappler). This rejection is respectfully traversed.

Kappler relates to providing protection against super antigen pathogens by administration of modified or mutated super antigen molecules which are said to illicit an antibody response against a super antigen without having the pathological effect of the super antigen. SEB mutants are mentioned in examples 6 and 7, but applicants do not see that Kappler discloses the claimed subject matter.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1-20 have been rejected as obvious under Section 103 from Nishi in view of Sasaki and Kappler. The rejection is respectfully traversed.

First, this rejection is inconsistent with the rejections based on Section 102. For example, if claim 1 were anticipated by each of the three references, as alleged in the Office Action, then a statement that claim 1 is obvious from the three references in combination makes no sense. Section 103 explicitly relates to subject matter which is **not** anticipated, and states that a "patent may not be obtained though the invention is not identically disclosed or described as set forth in Section 102..." A claim can be anticipated by a reference or it can be obvious from that reference, but it cannot be both anticipated and obvious from the same reference. In the present case, applicants' claims are neither anticipated nor obvious from the prior art.

Moreover, the rejection based on alleged obviousness is also inconsistent with the rejection based on the first paragraph of Section 112. The claimed subject matter cannot be both obvious to one of ordinary skill in the art at the time the invention was made (Section 103) and be non-enabling to those skilled in the art which have before them not only

the prior art but also the applicants' disclosure. In the present case, those skilled in the art would be able to fully practice applicants' invention (as noted above) based on applicants' disclosure and the knowledge of the prior art, but the claimed invention would not have been obvious from the prior art **without** recourse to applicants' specification.

Applicants respectfully submit that there would have been no **reason** to attempt to take bits and pieces from the three references and combine them in any particular way. Applicants also respectfully submit that the improvements achieved according to the present invention could not have been reasonably expected from a consideration of the prior art.

Withdrawal of the rejection is in order and is respectfully requested.

The prior art documents of record and not relied upon by the PTO have been noted, along with the implication that such documents are deemed by the PTO to be insufficiently material to warrant their application against any of applicants' claims.

Applicants believe that all issues raised in the Official Action have been addressed above in a manner that should lead to patentability of the present application.

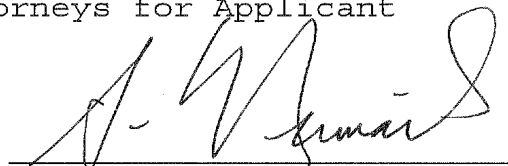
Appln. No. 10/551,263
Amd. dated June 12, 2008
Reply to Office Action dated: December 12, 2007

Favorable consideration and early formal allowance are
respectfully requested.

Respectfully submitted,

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By

A handwritten signature in black ink, appearing to read "S. Neimark", written over a horizontal line.

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